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Summary of Safety and Effectiveness

Applicant or Sponsor: Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Michelle L. McKinley
Regulatory Specialist

Proprietary Name: M2a™ Acetabular System

Common or Usual Name: acetabular cup prosthesis

Classification Name: prosthesis, hip, semi-constrained, metal/polymer, uncemented (888.3330)

Device Product Code: 87 KWA

Substantially Equivalent Devices: M2a™ Acetabular System, McKee Farrar, DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners

Device Description:

Acetabular Shell

The 38mm M2a™ acetabular cup is cobalt chromium one-piece cup. The hemispherical shape of the acetabular cup closely matches the natural acetabulum, which leads to minimal bone removal in preparation for implantation. The inner surface of the cup is the bearing surface.

Modular Femoral Head

The 38mm M2a™ acetabular cup utilizes a 38mm cobalt-chromium (Co-Cr-Mo) modular femoral head. The modular heads may be used in conjunction with any of Biomet's commercially available Type I taper femoral components.

Intended Use:

The M2a™ Acetabular System is indicated for use in patients requiring total hip replacement due to the following:

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639 ■ FAX
219.267.8137 ■ E-MAIL
biomet@biomet.com

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a.) Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, osteoarthritis, slipped capital epiphysis, subcapital fractures, and traumatic arthritis
b.) Rheumatoid arthritis
c.) Correction of functional deformity
d.) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
e.) Revision of previously failed total hip arthroplasty.

Basis of Substantial Equivalence:

In terms of overall design and intended use, the M2a™ Acetabular System is equivalent to all other total hip acetabular components. Specifically, the geometry, materials, and fixation enhancements are similar to the following devices:

1. M2a™ Acetabular System: K993438, K003363
2. McKee Farrar: Pre-amendment Device
3. DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners: K003523

Mechanical testing was also used to determine substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Michelle L. McKinley
Regulatory Specialist
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K011110
Trade Name: M2a™ Acetabular System
Regulatory Number: 888.3330
Regulatory Class: Class III
Product Code: KWA
Dated: March 30, 2001
Received: April 11, 2001

Dear Ms. McKinley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

DMitchell for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number if Known: K011110
Device Name: M2a™ Acetabular System

The M2a™ Acetabular System is indicated for used in patients requiring total hip replacement due to the following:

a.) Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, osteoarthritis, slipped capital epiphysis, subcapital fractures, and traumatic arthritis
b.) Rheumatoid arthritis
c.) Correction of functional deformity
d.) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
e.) Revision of previously failed total hip arthroplasty.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over the Counter Use _____
(Per CFR 801.109) (Optional Format 1-2-96)

Postmarket controls for CMW

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011110